IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

CASE NO. 3:10-CV-154
Jordan/Shirley

DOUGLAS TAYLOR,
PLAINTIFF
v.

LUPIN, LTD., AND LUPIN PHARMACEUTICALS, INC.
DEFENDANTS.

COMPLAINT FOR DAMAGES
DEMAND FOR JURY TRIAL

DOUGLAS TAYLOR, Plaintiff, by and through his undersigned attorneys, states and alleges as follows:

I. PARTIES

1. DOUGLAS TAYLOR, Plaintiff, (hereinafter referred to as "Plaintiff") is an individual of the full age of majority who is a resident and citizen of Lenoir City, Tennessee

2. Plaintiff brings this action for the purpose of recovering all damages allowable by law for personal injuries he suffered as a result the ingestion of a pharmaceutical drug, Ramipril, manufactured by Defendants.

3. Defendant Lupin, Ltd., is a corporation with its corporate office located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office located at Lupin, Ltd., 159 CST Road, Kalina, Santacruz (E), Mumbai, 400 098, India, and is the parent corporation of Lupin Pharmaceuticals, Inc.

4. Lupin Pharmaceuticals, Inc., is a wholly owned U.S. subsidiary of Lupin Ltd., and is a Maryland corporation. The principal office for Lupin Pharmaceuticals, Inc., is located at the 21st Floor, 111 S. Calvert Street, Baltimore, MD 21202. The registered agent for service of process is Vinita Gupta, 21st Floor, 111 S. Calvert Street, Baltimore, Maryland 21202.

5. References in this Complaint to "DRUG COMPANY DEFENDANTS" and/or "LUPIN" include both LUPIN, LTD., and LUPIN PHARMACEUTICALS, INC.

6. At all times material hereto, LUPIN was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, RAMIPRIL tablets in the State of Tennessee and in interstate commerce.

7. At all relevant times, DRUG COMPANY DEFENDANTS were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

8. At all times relevant hereto, DRUG COMPANY DEFENDANTS were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising the pharmaceutical drugs known and/or branded as ALTACE and/or the generic equivalent, RAMIPRIL in the State of Tennessee and in interstate commerce.

9. At all relevant times, DRUG COMPANY DEFENDANTS did manufacture, create, design, assemble, test, label, sterilize, package, distribute, promote, supply, market, sell, advertise, and/or otherwise distribute in the State of Tennessee and in interstate commerce RAMIPRIL tablets.

10. At all relevant times, DRUG COMPANY DEFENDANTS sold, delivered and/or distributed such products for ultimate sale and/or use interstate commerce within the United States and the State of Tennessee by consumers, including Plaintiff.

II.

JURISDICTION AND VENUE

11. Venue is proper in this District pursuant to 28 U.S.C.A. § 1391. Drug Company Defendants marketed, advertised and distributed RAMIPRIL and false and misleading information in this district, thereby receiving substantial financial benefit and profits from sales of RAMIPRIL in this district; and Plaintiff resides in this district; thus, venue is proper.

12. Drug Company Defendants conduct substantial business in the State of Tennessee and within this Federal Judicial District, advertises in this district, distributes RAMIPRIL in this district, receives substantial compensation and profits from sales of RAMIPRIL in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

13. Drug Company Defendants conducted business in the State of Tennessee through pharmaceutical sales representatives conducting business in the State

of Tennessee on behalf of Drug Company Defendants and because Drug Company Defendants was engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, RAMIPRIL; thus, there exists a sufficient nexus between the Drug Company Defendants forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Tennessee.

14. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Drug Company Defendants, because Drug Company Defendants are present in the State of Tennessee such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

III.

STATEMENT OF FACTS

15. This case involves the pharmaceutical drug Ramipril which belongs to a family of drugs known as "Angiotensin-Converting Enzyme inhibitors" or "ACE inhibitors."

16. ACE inhibitors inhibit a biochemical pathway that constricts blood vessels and are used to treat high blood pressure.

17. The earliest ACE inhibitors, dating back to the 1960s, were based on the venom of the Brazilian Viper, which was known to reduce blood pressure.

18. Synthetic ACE inhibitors have been developed by making structural modification to the viper venom and to successive generations of ACE inhibitors, including ENALAPRIL.

19. RAMIPRIL'S immediate predecessor is an ACE inhibitor known as ENALAPRIL.

20. On March 18, 2005, Lupin filed an Abbreviated New Drug Application (ANDA) with the FDA seeking approval for a generic version of RAMIPRIL.

21. RAMIPRIL'S principal label, known as the "Package Insert" was developed by the drug company Defendants and accompanied all prescription drug products and/or samples. By federal law, the labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, contraindications, warnings, precautions and side effects.

22. Drug Company Defendants failed to fully, truthfully and accurately communicate the risks of RAMIPRIL, and/or ACE inhibitors, and as a result intentionally and fraudulently mislead the medical community, physicians, Plaintiff's physician and Plaintiff about the risks of severe side effects described herein, including but not limited to Stevens Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TENS) associated with the use of RAMIPRIL.

23. Drug Company Defendants caused its Package Insert to be disseminated to Plaintiff's Physicians and other members of the medical community. Drug Company Defendant's Package Insert reports

minimized the risk of a severe cutaneous reactions and severe side effects described herein, including but not limited to Stevens Johnson Syndrome in patients ingesting RAMIPRIL, and/or ACE inhibitors, despite available literature that Drug Company Defendants should have found and reported stating a statistically significant higher risk for such reactions.

24. DRUG COMPANY DEFENDANTS fraudulently and aggressively promoted RAMIPRIL to physicians for use in patients, such as Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications from the DRUG COMPANY DEFENDANTS sales force, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures as these materials downplayed the significance of the adverse effects of RAMIPRIL and the risk of Stevens-Johnson Syndrome and severe cutaneous reactions.

25. Drug Company Defendants knew there was substantial and mounting evidence of the enormous risk of serious systemic reactions such as hypersensitivity syndrome, SJS and TEN associated with ACE inhibitors. Yet, despite the scientific and epidemiological evidence that would compel Drug Company Defendants' to issue warnings to physicians and patients, Drug Company Defendants consciously decided to ignore this pertinent information when it came time to protect the health of patients in the United States from the severe cutaneous adverse events associated with this drug.

26. Despite accounts of severe cutaneous reactions and severe side effects as described herein including but not limited to Stevens-

Johnson Syndrome and TENS reported directly to the Drug Company Defendants, and reports in the literature, the Drug Company Defendants failed to report the true and accurate risk of said side effects to the Plaintiff's physicians and the medical community and regularly represented in its advertising and promotional messages to said individuals that the risks of cutaneous adverse reactions associated with exposure to ACE inhibitors was minimal when in fact it was significantly greater.

27. The RAMIPRIL manufactured and/or supplied by Drug Company Defendants was defective due to inadequate pre-marketing and post-marketing warnings or instructions because, after Drug Company Defendants knew or should have known of the risk of injury from RAMIPRIL, Drug Company Defendants failed to provide adequate warnings to Plaintiff's physicians, Plaintiff, physicians and the medical community who prescribed the drug, and to their patients who were the ultimate consumers of the product. Yet despite their inadequate post-marketing warnings and instructions to said persons Drug Company Defendants continued to aggressively promote the product thereby making Drug Company Defendants strictly liable for failure to warn.

28. Plaintiff was prescribed, and was dispensed Ramipril, and ingested Drug Company Defendant's RAMIPRIL pursuant to instruction.

29. Thereafter, Plaintiff developed a skin condition due to an adverse reaction to Drug Company Defendants' drug which caused Plaintiff to develop a skin rash, and/or itching, and/or discoloration of the

skin, and/or exfoliation of the skin, and/or shedding of hair, and/or shedding of nails, and/or loss of pigmentation of the skin, and/or hives and/or swelling and/or lesions, and/or burns to Plaintiff's body, and/or scarring from said lesions or burns; and/or injuries affecting the bodily mucous membranes, and/or loss or damaged eyesight; and/or permanent damage to internal organs; and/or hypersensitivity, and/or Stevens Johnson Syndrome, and/or Toxic Epidermal Necrolysis syndrome causing Plaintiff to require medical treatment for said condition.

30. Under the FDA schema, Drug Company Defendants holds an Abbreviated New Drug Application, which allows Drug Company Defendants to manufacture, sell, market and distribute RAMIPRIL, which was ingested by Plaintiff herein.

31. Plaintiff ingested RAMIPRIL, as prescribed and ordered by his physician.

32. Plaintiff's ingestion of Drug Company Defendant's RAMIPRIL caused his injuries.

33. Plaintiff's physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated by Drug Company Defendants.

34. Drug Company Defendants provided misleading information about the true risks associated with the use of Drug Company Defendant's RAMIPRIL to the medical community, Plaintiff's Physician, and Plaintiff (and other foreseeable users similarly situated).

35. Plaintiff used Drug Company Defendant's pharmaceutical drug RAMIPRIL

without substantial change in condition of the drug between the time of design and manufacture of the drug and the time Plaintiff used the drug as directed.

36. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the Drug Company Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Drug Company Defendants' RAMIPRIL and the ingestion of RAMIPRIL to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of the drug.

37. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries they suffered caused by the ingestion of Drug Company Defendants' RAMIPRIL.

IV. ALLEGATIONS

38. Under the FDA schema, Drug Company Defendants hold an Abbreviated New Drug Application (ANDA), which allows Drug Company Defendants to market and distribute a generic formulation of RAMIPRIL.

39. At all relevant times hereto, Drug Company Defendants did not investigate the accuracy of its' RAMIPRIL drug label.

40. Drug Company Defendants were negligent in failing to report published articles and overwhelming scientific evidence of

increased risks of severe side effects described herein including SJS and TEN associated with RAMIPRIL therapy to the FDA, healthcare providers or patients in the U.S. The regulations required them to report these papers, undertake action to add new warnings to the package insert for RAMIPRIL, and to report any foreign regulatory actions that included new warnings or new safety information for the product.

41. At all relevant times hereto, Drug Company Defendants did not review the medical literature for the RAMIPRIL

42. Drug Company Defendants are under a duty to ensure that its' RAMIPRIL label is accurate.

43. Under the Code of Federal Regulations, Drug Company Defendants, as an ANDA holder, had a duty to ensure its RAMIPRIL warnings to the medical community were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by RAMIPRIL, the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

44. Under the Code of Federal Regulations, if Drug Company Defendants, as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Drug Company Defendants must report that information to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users RAMIPRIL to ensure that its warnings are continually accurate and adequate.

45. Drug Company Defendants breached its duty to the medical community,

Plaintiff's Physician, Plaintiff, and other foreseeable users similarly situated because it failed to RAMIPRIL warnings to the medical community, Plaintiff's physician, Plaintiff, other foreseeable users similarly situated were accurate and adequate.

46. Drug Company Defendants breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of RAMIPRIL, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of RAMIPRIL.

47. Drug Company Defendants breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by RAMIPRIL, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

48. Drug Company Defendants breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning severe side effects as described herein, including but not limited to SJS and TENS, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of RAMIPRIL.

49. If a generic drug company learns of side effects, risks or misleading and

inaccurate information in the RAMIPRIL label, it must request and/or submit labeling revision for the drug, under the FDA schema.

50. Drug Company Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in its RAMIPRIL label and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff's physicians and other foreseeable users.

51. At all times material hereto, Drug Company Defendants were aware of the serious side effects caused by RAMIPRIL including, but not limited to, severe side effects described herein and failed to fulfill its obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users about the safety of the use of the drug.

52. At all times material hereto, Drug Company Defendants knew or should have known that physicians were **not** aware of or did not fully appreciate the seriousness of the risks associated with use of RAMIPRIL.

53. Drug Company Defendants knew or should have known that the package insert and the Physician Desk Reference monograph for RAMIPRIL did not adequately inform physicians about the risks of severe side effects described herein, and/or SJS or TENS associated with RAMIPRIL; yet, said Drug Company Defendants failed to communicate said information to the medical community, Plaintiff's physicians, Plaintiff or other foreseeable users alike, and in doing so, mislead the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users about the safety of the use

of this drug.

54. Drug Company Defendants knew, or should have known through the exercise of reasonable care, that the package insert for RAMIPRIL substantially understated the prevalence of the risk of severe side effects described herein, SJS and TENS associated with RAMIPRIL.

55. Drug Company Defendants willfully and in wanton disregard of the rights of Plaintiff, failed to disclose and communicate material safety information regarding the risks of this drug to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed RAMIPRIL by a physician who was not aware of the risk of severe skin reactions, SJS and TENS.

56. Drug Company Defendants falsely and fraudulently represented to physicians, Plaintiff physicians, and to foreseeable users, including Plaintiff, that RAMIPRIL was safe to use and that permanent and severe side effects described herein, SJS and TENS were rare and/or infrequent.

57. Drug Company Defendants did not disclose or warn physicians about the actual prevalence of known side effects of RAMIPRIL when RAMIPRIL is used as marketed by Drug Company Defendants, or when used in patients such as of Plaintiff of RAMIPRIL, all of which were foreseeable.

58. At the time Drug Company Defendants made the above-described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

59. Plaintiff's serious and permanent injuries, as described above, came about as

a foreseeable and proximate result of Drug Company Defendant's failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of RAMIPRIL.

60. In doing the acts alleged in this Complaint, Drug Company Defendants acted with oppression, fraud, and malice and Plaintiff are therefore entitled to punitive damages to deter Drug Company Defendants and others from engaging in similar conduct in the future.

61. As a proximate result of the fraud and deceit of Drug Company Defendants, Plaintiff sustained the injuries and damages as described in this Complaint.

62. Drug Company Defendants had an absolute duty to disclose the true facts regarding the safety of RAMIPRIL to the medical community, to physicians and their patients, pharmacists, and the generic RAMIPRIL industry, which it negligently and/or intentionally failed to do.

63. Drug Company Defendants had a duty to ensure that it had a reasonable basis for making the representations regarding the safety, efficacy, risks and benefits of RAMIPRIL, were accurate and was under at duty to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations, all of which it negligently and/or intentionally failed to do.

64. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Drug Company Defendants.

65. Drug Company Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

66. At all times mentioned in this Complaint, the Drug Company Defendants had a duty to truthfully, accurately and fully disclose information and data which would reflect that the risks of severe skin reactions, SJS and TENS clearly outweighed the utility of the RAMIPRIL or its therapeutic benefits to patients.

67. The Drug Company Defendants were negligent, and breached its duties owed to the medical community, Physicians, Plaintiff's physician, Plaintiff and other like foreseeable users, with respect to RAMIPRIL in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that RAMIPRIL was frequently prescribed for the use of Plaintiff and other consumers of the drug, Drug Company Defendants failed to accompany the RAMIPRIL with adequate warnings and instructions regarding the adverse side effects associated with the use of RAMIPRIL; and

(b) Drug Company Defendants failed to perform adequate testing on RAMIPRIL; and

(c) Despite knowledge of hazards, Drug Company Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the RAMIPRIL; and

(d) Despite knowledge of hazards, Drug Company Defendants failed to adequately warn Plaintiff's physicians or Plaintiff that the use of RAMIPRIL could result in serious side effects, including severe skin reactions, SJS and TENS; and

(e) Despite the fact that the Drug Company Defendants knew or should have known that RAMIPRIL caused unreasonably dangerous side effects, Drug Company Defendants failed to adequately disclose the known or knowable risks associated with RAMIPRIL and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare and the safety and welfare of other foreseeable users of RAMIPRIL.

(f) Despite the fact that the Drug Company Defendants knew or should have known that RAMIPRIL caused unreasonably an increased risk of severe skin reactions Drug Company Defendants failed to adequately disclose the known or knowable risks associated with RAMIPRIL and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare and the safety and welfare of other like foreseeable users of RAMIPRIL.

68. As a result of the negligence of the Drug Company Defendants and its willful and wanton misconduct, RAMIPRIL was prescribed to Plaintiff for his use; and was used as prescribed; thereby, causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint.

69. The negligence and the willful and wanton misconduct of the Drug Company Defendants was a proximate cause of Plaintiff's harm and injuries that Plaintiff has suffered and will continue to suffer.

70. At all times mentioned in this Complaint, RAMIPRIL was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the Drug Company Defendants.

71. RAMIPRIL was "defective" and "unreasonably dangerous" when the drug was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the following respects:

(a) At the time RAMIPRIL left the control of the Drug Company Defendants it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the RAMIPRIL breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seek recovery herein.

(b) RAMIPRIL was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time RAMIPRIL left the possession of the Drug Company Defendants, and that such risks clearly

outweighed the utility of RAMIPRIL or its therapeutic benefits.

(c) At the time RAMIPRIL left the control of the Drug Company Defendants the drug possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the RAMIPRIL left the possession of the Drug Company Defendants. Specifically, although the Drug Company Defendants was well aware that RAMIPRIL could potentially cause severe side effects described herein, SJS and TENS, warnings of such adverse health conditions were either not included on the package insert for RAMIPRIL and/or the warnings were inadequate to inform reasonably prudent physicians and foreseeable users of the risks. The Drug Company Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of RAMIPRIL.

(d) The Drug Company Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the RAMIPRIL taking into account the characteristics of the RAMIPRIL, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases RAMIPRIL, such as the Plaintiff.

(e) The RAMIPRIL manufactured and supplied by the Drug Company Defendants was further defective due to inadequate post-marketing warning or instruction because, after the Drug Company Defendants knew or should have known of the risks of injury from RAMIPRIL associated with the use as commonly prescribed, Drug Company Defendants failed to promptly respond to and adequately warn about severe skin reactions, SJS and TENS to foreseeable users.

(f) The RAMIPRIL manufactured and supplied by the Drug Company Defendants was further defective due to inadequate post-marketing warning or instruction because, after the Drug Company Defendants knew or should have known of the risks of injury from RAMIPRIL associated with the use as commonly prescribed, Drug Company Defendants failed to promptly respond to and adequately warn about an increased risk as reported in the medical literature for severe skin reactions, SJS and TENS posed to patients, who were foreseeable users of the drug.

72. The Drug Company Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seek recovery.

73. A reasonably competent physician who prescribed RAMIPRIL and a reasonably competent Plaintiff who consumed RAMIPRIL would not realize its dangerous condition.

74. The reasonably foreseeable use of RAMIPRIL involved substantial dangers not readily recognizable by Plaintiff's physician, who acted as an ordinary reasonable and prudent physicians would, when prescribing RAMIPRIL to an ordinary, reasonable and prudent patient, like Plaintiff.

75. The Drug Company Defendants knew that RAMIPRIL which was to be prescribed by physicians and used by foreseeable users without inspection for defects in RAMIPRIL or in any of its components or ingredients and that RAMIPRIL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

76. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of RAMIPRIL, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

77. These defects caused serious injuries to Plaintiff when the RAMIPRIL was used in its intended and foreseeable manner, and in the manner recommended by the Drug Company Defendants or in a non-intended manner that was reasonably foreseeable.

78. Drug Company Defendants knew that its warranties regarding safety for the use, would be relied upon by ordinary, reasonable and prudent physicians who would share that information with other physicians in their community and that eventually physicians would come to rely on Drug Company

Defendant's express warranties concerning the safety of RAMIPRIL.

79. Drug Company Defendants' express warranties about the safety of RAMIPRIL were false and intentionally and/or negligently misleading.

80. Drug Company Defendants also knew that the risks of potentially severe side effects described herein, including SJS and TENS when RAMIPRIL is used were much greater than most physicians realized. By failing to give adequate warnings about the properties of RAMIPRIL and the risk of the use that is associated with those properties, the Drug Company Defendants breached implied warranties of merchantability and fitness for the ordinary use of RAMIPRIL.

81. At all times mentioned in this Complaint, the Drug Company Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold RAMIPRIL and prior to the time it was used by Plaintiff, the Drug Company Defendants impliedly warranted to Plaintiff and to Plaintiff physicians that the RAMIPRIL was of merchantable quality and safe and fit for the use for which it was intended.

82. Plaintiff relied on the skill and judgment of the Drug Company Defendants in using RAMIPRIL as prescribed.

83. RAMIPRIL was unsafe and unfit for its intended use; was not of merchantable quality, as warranted by the Drug Company Defendants, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. RAMIPRIL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that

were either known or reasonably scientifically knowable at the time of distribution. As a result, the drug proximately caused Plaintiff to sustain damages and injuries as alleged in this Complaint.

84. By virtue of Drug Company Defendant's acts and omissions, Drug Company Defendants are liable to Plaintiff because Drug Company Defendants' acts and omissions have proximately caused Plaintiff to suffer permanent injuries.

85. Plaintiff used RAMIPRIL, which was provided to him, respectively, in a condition that was substantially the same as the condition in which it was manufactured and sold.

86. Drug Company Defendants through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking RAMIPRIL; and thus, the running of any applicable statute of limitations has been tolled by reason of Drug Company Defendants' fraudulent concealment.

87. As a result of Drug Company Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Drug Company Defendant's acts, omissions, and misrepresentations.

88. As a direct and proximate result of the acts and omissions of Drug Company Defendants, the Plaintiff was prevented from pursuing his normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of his ordinary pursuits and enjoyments of

life.

89. Equity dictates that this Court provide the Plaintiff a remedy that provides Plaintiff with sufficient information and medical monitoring appropriate for Plaintiff to make informed decisions related to Plaintiff's physical well-being. Absent such notice Plaintiff will be irreparably harmed.

90. Plaintiff are also entitled to any procedural protections deemed necessary and appropriate to protect Plaintiff's legal interests.

91. Based upon the allegations set forth herein, the Drug Company Defendants' knew of facts that created a high degree of risk of physical harm to the Plaintiff and yet the Drug Company Defendant's deliberately proceeded to act in conscious disregard or indifference to that risk, and therefore an award of punitive damages is warranted.

92. Plaintiff is entitled to recovery an award for the injuries caused by the Drug Company Defendants.

93. As a direct and proximate result of the aforesaid acts of and/or omissions by the Drug Company Defendants, Plaintiff, has:

(a) Suffered severe and permanent injuries, which he will be forced to endure for the remainder of Plaintiff life;

(b) Suffered physical impairment and disfigurement; and

(c) Suffered physical pain and suffering;

(d) Suffered mental pain and suffering; and

(e) Suffered from loss of enjoyment of life; and

(f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiff injuries; and

(g) Incurred attorney's fees and expenses of litigation related to this

action.

94. Drug Company Defendant's actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self interest and personal gain and evidenced a specific intent to cause harm to Plaintiff.

IV.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

95. The running of any statute of limitations has been tolled by reason of Drug Company Defendants' fraudulent concealment. Drug Company Defendants, through failing to disclose a known defect to Plaintiff's physicians and/or Plaintiff, and misrepresenting their drug as safe for its intended use, actively concealed from said individuals the true risks associated with the use of the drug.

96. As a result of Drug Company Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not reasonably known or have learned through reasonable diligence of the manufacturing defect and that has been exposed to the risks alleged herein and that those risks were a direct and proximate result of Drug Company Defendants' acts and omissions.

97. Furthermore, Drug Company Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of the drug. Drug Company Defendants were under a duty to disclose the true character, quality, and nature of the drug because this was non-public

information over which the Drug Company Defendants have, and continue to have, exclusive control, and because Drug Company Defendants knew that this information was not available to the Plaintiff or their physicians. In addition, the Drug Company Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

98. Plaintiff had no knowledge that Drug Company Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Drug Company Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action. Plaintiff, nor Plaintiff's physicians, could have possibly determined the nature, extent and identity of related health risks dealing with the manufacturing defect of Drug Company Defendant's drug and reasonably relied on Drug Company Defendants' to disseminate truthful and accurate safety and efficacy information about its drug and warm of the side effects complained of herein.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

V.

WRONGFUL CONDUCT

COUNT 1

STRICT PRODUCTS LIABILITY

99. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained

in this Complaint with the same force and effect as if fully set forth herein.

100. At all relevant times the Drug Company Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling RAMIPRIL.

101. Drug Company Defendants, developed, marketed and distributed RAMIPRIL to the general public even after learning of the design and manufacturing defects that threatened the intended use of the drug.

102. Drug Company Defendants' RAMIPRIL was defective and unreasonably dangerous and was expected to and did reach Plaintiff without substantial change in the drug.

103. At all times mentioned in this Complaint, RAMIPRIL was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the Drug Company Defendants.

104. Drug Company Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the drug created a high risk of bodily injury and serious harm.

105. The dangerous propensities of RAMIPRIL were known or scientifically knowable, through appropriate research and testing, to the Drug Company Defendants at the time said Drug Company Defendants distributed, supplied, or sold the drug, and not known to ordinary physicians who would be expected to prescribe the drug for their patients, or their patients.

106. RAMIPRIL as distributed by the Drug Company Defendants, was defective and unreasonably dangerous inasmuch as the RAMIPRIL was not accompanied by warnings and instructions that were appropriate and adequate to render the

drugs reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the products for the RAMIPRIL therapy.

107. Prior to the manufacturing, sale and distribution of said drug products, Drug Company Defendants knew that its RAMIPRIL was in a defective condition as previously described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries.

108. Drug Company Defendants had prior notice and knowledge from several sources, prior to the date of dispensing of said drug products to Plaintiff, that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such said consumers of said drug were unreasonably subjected to risk of injury or death from the consumption of said drug.

109. Despite such knowledge, Drug Company Defendants for the purpose of enhancing Drug Company Defendant's profits, knowingly and deliberately failed to warn the public, including Plaintiff, of the extreme risk of physical injury occasioned by said defects inherent in said drug. Drug Company Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of the drug with knowledge that consumers would be exposed to serious danger in order to advance Drug Company Defendant's own pecuniary interest.

110. RAMIPRIL was "defective" and "unreasonably dangerous" when the product initially was patented, and subsequently when it was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the

following respects:

(a) At the time RAMIPRIL left the control of the Drug Company Defendants it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the product breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.

(b) RAMIPRIL was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the product left the possession of the Drug Company Defendants, and that such risks clearly outweighed the utility of the product or its therapeutic benefits.

(c) At the time RAMIPRIL left the control of the Drug Company Defendants it possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the product left the possession of the Drug Company Defendants. Specifically, although the Drug Company Defendants were well aware that RAMIPRIL could potentially cause

severe side effects described herein, SJS and TENS, and in fact, had significantly greater prevalence and severity of these side effects than revealed by the manufacturer; and/or warnings of such adverse health conditions were either not included on the package insert for these products or they were not adequate to inform reasonably prudent physicians and consumers. The Drug Company Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of RAMIPRIL.

(d) The Drug Company Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the product taking into account the characteristics of the product, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the product, such as the Plaintiff.

(e) The RAMIPRIL manufactured and supplied by the Drug Company Defendants was further defective due to inadequate post-marketing warning or instruction because, after the Drug Company Defendants knew or should have known of the risks of injury from RAMIPRIL associated with the use as commonly prescribed, they failed to promptly respond to and adequately warn about severe side effects described

herein, SJS and TENS.

111. The Drug Company Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery. A reasonably competent physician who prescribed RAMIPRIL and a reasonably competent Plaintiff who consumed RAMIPRIL would not realize its dangerous condition.

112. The Drug Company Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of RAMIPRIL that caused the damages for which Plaintiff seeks recovery.

113. The reasonably foreseeable use of RAMIPRIL involved substantial dangers not readily recognizable by the ordinary physician who prescribed RAMIPRIL or the patient, like Plaintiff, who consumed RAMIPRIL.

114. The Drug Company Defendants knew that the RAMIPRIL was to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that RAMIPRIL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

115. Plaintiff and Plaintiff physicians did not know, nor had reason to know, at the time of the use of RAMIPRIL, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

116. These defects caused serious injuries to Plaintiff when the product was used in its intended and foreseeable manner, and in the manner recommended by the Drug Company Defendants and/or in a non-intended manner that was

reasonably foreseeable.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 2

BREACH OF EXPRESS WARRANTY

117. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

118. Drug Company Defendants' concealment and failure to warn through promotional statements and product literature expressly warranted to Plaintiff that RAMIPRIL was safe and effective.

119. In response to these promises and express statements, Plaintiff and Plaintiff physicians relied on such affirmations and warranties to Plaintiff through Plaintiff physicians.

120. RAMIPRIL does not conform to those express representations in light of recently discovered disclosures and information previously withheld by Drug Company Defendants. Drug Company Defendants' express warranty through its false statements failed to disclose design, manufacturing and safety defects inherent in the drug.

121. Drug Company Defendants breached its warranty of RAMIPRIL by continuing sales and marketing campaigns highlighting the safety of its drug, while it knew of the design, manufacturing and safety defects and the risk of contracting a

severe skin reaction, SJS and/or TENS posed by RAMIPRIL.

122. As a direct and proximate result of Drug Company Defendant's breach of its express warranty, Plaintiff suffered bodily and mental injury, harm, other compensable injury and economic losses, compensable through this Court.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 3

NEGLIGENCE

123. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

124. Drug Company Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of RAMIPRIL to ensure the safety of its drug and to ensure that the consuming public, including the Plaintiff and Plaintiff physicians and agents, obtained accurate information and instructions for the use of RAMIPRIL.

125. As a direct and proximate cause of Drug Company Defendants' conduct, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

126. The Drug Company Defendants owed a duty toward foreseeable users of RAMIPRIL including the Plaintiff, to exercise reasonable care to ensure that

the RAMIPRIL it manufactured and/or distributed were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks of a severe skin reaction, SJS and/or TENS, inherent in such use.

127. Drug Company Defendants failed to exercise reasonable care in testing RAMIPRIL for side effects in ordinary and foreseeable users; and failed to disseminate to physicians information concerning the effects of RAMIPRIL which was accurate, not misleading, and otherwise adequate to enable physicians to make informed choices concerning the use of RAMIPRIL.

128. Drug Company Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the drug into the stream of interstate commerce in that Drug Company Defendants knew or should have known that RAMIPRIL created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

129. The dangerous propensities of RAMIPRIL, as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Drug Company Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for Plaintiff and other patients, similarly situated.

130. The information the Drug Company Defendants disseminated to physicians concerning RAMIPRIL was, in fact, inaccurate, misleading, and otherwise

inadequate, as described above.

131. As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested, as prescribed, RAMIPRIL, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by Drug Company Defendants through third parties or related entities.

132. The Drug Company Defendants was negligent, and breached duties owed to Plaintiff with respect to RAMIPRIL in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Drug Company Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of RAMIPRIL;

(b) Drug Company Defendants failed to conduct adequate testing; and

(c) Despite knowledge of hazards, Drug Company Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product; and

(d) Despite knowledge of hazards, they failed to adequately warn Plaintiff physicians or Plaintiff that the use of RAMIPRIL could result in a severe side effects as described herein, SJS and/or TENS; and

(e) Despite the fact that the Drug Company Defendants knew or should have known that RAMIPRIL caused unreasonably dangerous side effects, Drug Company Defendants failed to adequately disclose the known or knowable risks associated with RAMIPRIL as set forth above; Drug Company Defendants willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff safety or welfare.

133. As a result of the negligence of the Drug Company Defendants and its willful and wanton misconduct, RAMIPRIL was prescribed to Plaintiff for the use and was used by the Plaintiff, thereby causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this Complaint.

134. The negligence and the willful and wanton misconduct of the Drug Company Defendants was a proximate cause of Plaintiff's harm and injuries that Plaintiff has suffered and will continue to suffer as previously described.

135. In the alternative, Drug Company Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing Drug Company Defendants' RAMIPRIL drug. Furthermore, the economic damages and physical harm caused by Drug Company Defendants' conduct would not have occurred had Drug Company Defendants exercised the high degree of care imposed upon it and Plaintiff therefore pleads the doctrine of *res ipsa loquitur*.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 4

MISREPRESENTATION BY OMISSION

136. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

137. Drug Company Defendants misrepresented the soundness and reliability of RAMIPRIL to physicians and the general public through promotional and marketing campaigns. It misrepresented that RAMIPRIL was safe and/or effective when used as instructed, when, in fact, it was dangerous to the health of patients. Drug Company Defendants continued these misrepresentations for an extended period of time, without disclosing material information.

138. Drug Company Defendants took advantage of the limited opportunity Plaintiff had to discover Drug Company Defendants strategic and intentional concealment of the design, manufacturing and safety defects in RAMIPRIL.

139. At the time Drug Company Defendants promoted the drug at issue as safe and/or effective, Drug Company Defendants did not have adequate proof upon which to base such representations, and in fact, knew or should have known that drug was dangerous.

140. Drug Company Defendants concealed these design and manufacturing defects from the public by withholding information pertaining to the inherent design,

manufacturing and safety defects and high risks of a severe side effects as described herein, including SJS and/or TENS associated with Drug Company Defendants' RAMIPRIL drug and, instead presented RAMIPRIL as safe and reliable.

141. Drug Company Defendants intentional misrepresentations and omissions were made willfully, wantonly or recklessly to the Plaintiff to induce purchase of Drug Company Defendants' RAMIPRIL drug over other safer alternative drugs on the market.

142. Drug Company Defendants knew or should have known of the high risk Plaintiff would encounter by unwittingly agreeing to ingest Drug Company Defendants' defective drug.

143. Drug Company Defendants failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of RAMIPRIL and otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physician, and the public in general.

144. Drug Company Defendants made the aforesaid representations in the course of Drug Company Defendants business as designers, manufacturers, and distributors of RAMIPRIL despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning the aforesaid representations. Drug Company Defendants were aware that, without such information, it could not accurately make the aforesaid representations.

145. At the time the aforesaid representations were made, Drug Company Defendants intended to induce Plaintiff and/or Plaintiff's physicians to rely

upon such representations.

146. Said representations were made with the intent to defraud and deceive Plaintiff and/or Plaintiff's physicians and with the intent to induce Plaintiff and/or Plaintiff's physicians to rely upon the statements and to use RAMIPRIL in order to reap the profits from the sale of the drug.

147. Plaintiff and/or Plaintiff's physicians, at the time the representations were made, were unaware of their falsity and believed them to be true. In reasonable reliance thereon by Plaintiff and/or Plaintiff's physicians used RAMIPRIL, and as a result, Plaintiff has suffered, and will continue to suffer, injury, harm and economic loss alleged herein.

148. As a direct and proximate result of reliance upon Drug Company Defendants misrepresentations, Plaintiff has suffered and will continue to suffer injuries, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 5

NEGLIGENCE PER SE

149. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

150. As set forth above, Drug Company Defendants falsely and fraudulently

represented to Plaintiff's physicians, and through them to Plaintiff and members of the general public, that RAMIPRIL was safe and that a severe side effects as described herein including SJS and/or TENS were comparatively rare. These representations were, in fact, false. The true facts are that RAMIPRIL is not safe and is in fact, dangerous to the health and body of Plaintiff, and others similarly situated.

151. Drug Company Defendants made other representations about the safety and efficacy of RAMIPRIL, and its minimal side effects all as set forth above and incorporated herein by reference.

152. RAMIPRIL causes severe side effects as described herein including SJS and/or TENS far more frequently than represented, and Drug Company Defendants did not disclose or warn physicians about the actual prevalence of known side effects of RAMIPRIL.

153. Drug Company Defendants misrepresented the safety of RAMIPRIL and withheld warnings of the known side effects of RAMIPRIL when used as commonly prescribed by physicians as specifically required by 21 C.F.R. § 201.128.

154. When Drug Company Defendants made these representations, it knew that the representations were false. Drug Company Defendants made these representations with the intent to defraud and deceive Plaintiff's physicians; and, through them to defraud and deceive Plaintiff; and, with the intent to induce Plaintiff and Plaintiff's physicians to act in the manner alleged in this Complaint--that is to use RAMIPRIL instead of safer alternative pharmaceutical products on the market.

155. At the time Drug Company Defendants made the above described representations, and at the time Plaintiff and Plaintiff physicians took the actions alleged in this Complaint, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true. In reliance upon the representations, Plaintiff's physicians were induced to and did prescribe RAMIPRIL as described herein and Plaintiff did use RAMIPRIL as described herein.

156. If Plaintiff's physicians had known the actual facts Plaintiff would not have been prescribed RAMIPRIL and Plaintiff would not have taken RAMIPRIL.

157. The reliance of Plaintiff and Plaintiff's physicians upon the representations of Drug Company Defendants was justified because individuals and/or entities that appeared to be in the position to know the true facts made the representations.

158. As a proximate result of the fraud and deceit of Drug Company Defendants, Plaintiff sustained the injuries and damages described herein.

159. In doing the acts alleged in this Complaint, Drug Company Defendants acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages to deter Drug Company Defendants and others from engaging in similar conduct in the future. This wrongful conduct was done with the advance knowledge, authorization, or ratification of an officer, director, and/or managing agent of the Drug Company Defendants.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff

for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 6

NEGLIGENT MISREPRESENTATION

160. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

161. Drug Company Defendants owed a duty to disseminate accurate and adequate information concerning RAMIPRIL, and to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

162. Drug Company Defendants disseminated to physicians, through package inserts, and/or the publication of a PDR monograph, and/or otherwise mediums, information concerning the properties and effects of RAMIPRIL, with the intention that physicians would rely upon that information when making a decision concerning whether to prescribe RAMIPRIL for their patients.

163. Drug Company Defendants as a generic drug manufacturer and/or distributor, knew or ought to have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

164. Drug Company Defendants as a generic drug manufacturer and/or distributor,

knew or ought to have realized that the manufacturers and/or distributors of generic products, have a duty to ensure that the information contained in the package inserts accompanying their own generic prescription drug products is accurate, complete, not misleading, and otherwise adequate, and to monitor medical literature and post marketing adverse events and to report any data affecting the safety of the drug to the appropriate agency and/or alert the medical community, Plaintiff's physicians, and through them, Plaintiff.

165. Drug Company Defendants knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using RAMIPRIL and in writing prescriptions for "RAMIPRIL," would rely upon information disseminated to them by the manufacturer of the drug product, regardless of whether the prescriptions might be filled with either the name brand product or generic RAMIPRIL, and that many patients, in accordance with those prescriptions, would be likely to ingest generic RAMIPRIL.

166. Drug Company Defendants knew or ought to have realized that patients receiving prescriptions for generic RAMIPRIL written in reliance upon information they disseminated as the manufacturer/distributor of RAMIPRIL would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

167. Drug Company Defendants failed to exercise reasonable care to ensure that the information they disseminated to physicians concerning the properties and effects of RAMIPRIL was accurate and not misleading, and as a result disseminated information to physicians that was negligently and materially

inaccurate, misleading, and false.

168. As a proximate and foreseeable result of this negligence on the part of Drug Company Defendants the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon the negligently inaccurate, misleading, and false information disseminated by Drug Company Defendants, and believing the information to be true, prescribed for the Plaintiff the use of RAMIPRIL and Plaintiff ingested, per those prescriptions, RAMIPRIL, leading to Plaintiff's injuries.

WHEREFORE, Plaintiff pray for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 7

FRAUD AND MISREPRESENTATION

169. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

170. Drug Company Defendants had actual knowledge of facts, which demonstrated that representations in the package insert, and/or the PDR monograph, and/or literature Drug Company Defendants distributed concerning RAMIPRIL to physicians was false and misleading. Drug Company Defendants had an absolute duty to disclose the true facts regarding the safety of to physicians and their patients, pharmacists, and the generic RAMIPRIL industry, which they

negligently failed to do. Furthermore, Drug Company Defendants had a duty to ensure that it had a reasonable basis for making the representations described above, to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations concerning RAMIPRIL all of which Drug Company Defendants failed to do.

171. Important information regarding the risk of RAMIPRIL was in the exclusive control of Drug Company Defendants and was exclusively known by Drug Company Defendants. As part of its business and in the furtherance of Drug Company Defendants own interests, Drug Company Defendants disseminated information regarding RAMIPRIL to physicians and their patients, pharmacists and the generic RAMIPRIL industry and did so knowing that the safety of RAMIPRIL users depended on the accuracy of that information. Further, Drug Company Defendants knew and expected that recipients of that information would rely on the information that the recipients would take action based upon the information, and that individuals would be put in peril by such actions and that those individuals would suffer physical harm as a result.

172. Drug Company Defendants expressly and/or impliedly represented to Plaintiff, Plaintiff's physicians, pharmacists, the generic RAMIPRIL industry and members of the general public that RAMIPRIL was safe for use. The representations by Drug Company Defendants and Drug Company Defendants and the lack of them were, in fact, false. The true facts were that RAMIPRIL was not safe for use and was, in fact, dangerous to the health and body of Plaintiff.

173. Drug Company Defendants made the above-described representations with no

reasonable grounds for believing them to be true. Drug Company Defendants did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care both in ascertaining the accuracy of the information contained in those representations and in communicating the information. Further, Drug Company Defendants was aware that without such information it could not accurately make the above described representations.

174. The above misrepresentations or omissions were made to Plaintiff, Plaintiff's physicians, pharmacists, the generic pharmaceutical industry and the general public, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiff would not have suffered his injuries but for the above misrepresentations or omissions of Drug Company Defendants. Thus, Drug Company Defendants and Drug Company Defendants misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 8

FRAUD BY CONCEALMENT

175. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

176. The Drug Company Defendants, with the intention of deceiving physicians and

their patients, and to induce physicians to prescribe, and their patients to ingest, RAMIPRIL failed to adequately inform physicians, through package inserts and otherwise, that exposure to RAMIPRIL can lead to severe side effects described herein including SJS and TENS; but instead represented the RAMIPRIL therapy to be safe, said representations were unscientific and false.

177. At all times mentioned in this Complaint, Drug Company Defendants had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians the true facts concerning RAMIPRIL, that is, that RAMIPRIL was dangerous and defective and how likely it was to cause serious consequences to users, including injuries as described in this Complaint, and the true level of risk involved in prescribing RAMIPRIL for the purposes indicated. Drug Company Defendants made the affirmative representations set forth above to Plaintiff, Plaintiff's prescribing physicians, and the general public prior to the day Plaintiff was first prescribed and used RAMIPRIL while concealing the material facts set forth herein.

178. At all times mentioned in this Complaint, Drug Company Defendants had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians the true facts concerning RAMIPRIL that is that the use and exposure could cause severe skin reactions, SJS and/or TENS.

179. At all times mentioned in this Complaint, Drug Company Defendants and its predecessors intentionally, willfully and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from Plaintiff, with the intent to defraud as alleged in this Complaint.

180. At all times mentioned in this Complaint, neither Plaintiff nor Plaintiff's

physicians were aware of the facts set forth above; however, had Plaintiff and his Physician been aware of the facts set out herein, they would not have acted as they did, that is, and would not have utilized RAMIPRIL in the treatment of Plaintiff's condition.

181. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff were prescribed and took RAMIPRIL and subsequently became ill, thereby sustaining the injuries and damages as set forth in this Complaint.

182. In doing the acts alleged in this Complaint, Drug Company Defendants acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages and to Drug Company Defendant's wealth, and sufficiently large to be an example to others and to deter Drug Company Defendants and others from engaging in similar conduct in the future.

183. The Plaintiff's physician, in reliance upon the information disseminated by the Drug Company Defendants, and without knowledge of the undisclosed and knowingly concealed facts, determined that the benefits of prolonged RAMIPRIL therapy outweighed the risks for his patient, the Plaintiff, and prescribed a course of therapy for Plaintiff with RAMIPRIL.

184. As a proximate and foreseeable result of this knowing and fraudulent concealment of material facts on the part of the Drug Company Defendants, Plaintiff suffered grievous bodily injury and consequent economic and other loss when Plaintiff's physician, in reliance upon the information disseminated by the Drug Company Defendants, and in ignorance of the facts concealed from them in those disseminations, prescribed for the Plaintiff the use of

RAMIPRIL and Plaintiff ingested, per those prescriptions, RAMIPRIL, leading to Plaintiff's injuries.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 9

VIOLATION OF CONSUMER PROTECTION LAWS

185. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

186. By reason of the conduct as alleged herein, DRUG COMPANY DEFENDANTS violated the Tennessee Consumer Protection Act, T.C.A. § 47-18-104 by knowingly and intentionally inducing Plaintiff to use the drugs through the use of false and/or misleading advertising, representations and statements. The products failed to perform as represented and advertised, and in fact were unsafe.

187. The Drug Company Defendants induced the Plaintiff and Plaintiff's physician, through the use of false and/or misleading advertising, representations, and statements, as described above, to use and/or prescribe RAMIPRIL which Drug Company Defendants manufactured and/or distributed and sold, all in violation of the Tennessee Consumer Protection Act which proscribes, among other things:

i. Engaging in unfair trade practices as defined in the statute by

making false and misleading oral and written statements that have the capacity, tendency or effect of deceiving or misleading consumers;

ii. Engaging in unfair trade practices as defined in the statute by making representations that its' RAMIPRIL had an approval, characteristic, ingredient, use or benefit which they did not have, including but not limited to statements concerning the health consequences of the use of drugs;

iii. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceive or tend to deceive, including but not limited to, facts relating to the health consequences of the use of these drugs; and

iv. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of the drugs.

188. As a direct and proximate result of Drug Company Defendants' statutory violations, Plaintiff used RAMIPRIL as prescribed, which Plaintiff would not have used had Drug Company Defendants not issued false and/or misleading advertising, representations and statements.

189. By reason of such violations and pursuant to the laws and regulations of this state, Plaintiff is entitled to recover all of the monies paid for the products; to be compensated for the cost of medical care arising out of the use of the products; together with any and all actual damages recoverable under the law

including, but not limited to, past medical expenses, past wage loss, past pain, suffering, disability and emotional distress.

190. In addition, Plaintiff is entitled to recover fees and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.

191. Drug Company Defendants marketed to physicians in a manner calculated to increase sales of the drug and resultant profits to the drug company at the expense of, and in conscious disregard for, the health and safety of Plaintiff, and other patients alike, as safer and more effective alternative treatments existed.

192. The conduct of the Drug Company Defendants undertaken consciously and with notice, evinces a willful, wanton, and conscious disregard for the rights, healthy, and safety of patients, including the Plaintiff, who would be expected to be induced, by that conduct, to ingest RAMIPRIL leading to grievous, debilitating, and potentially permanent personal injury.

193. As a direct and proximate result of the wrongful acts of the Drug Company Defendants, Plaintiff developed severe side effects as described herein, including SJS and/or TENS and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; has incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; has suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 10

BREACH OF IMPLIED WARRANTIES

194. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

195. The Drug Company Defendants knew that most physicians who prescribed RAMIPRIL were not aware of the serious side effects as described herein including SJS and/or TENS associated with use of RAMIPRIL. The Drug Company Defendants also knew that the risks of said side effects when RAMIPRIL is used were much greater than most physicians realized. By failing to give adequate warnings about these side effects of RAMIPRIL and the risk of the use that is associated with those side effects, the Drug Company Defendants breached implied warranties of merchantability and fitness for the ordinary use of RAMIPRIL.

196. At all times mentioned in this Complaint, the Drug Company Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold RAMIPRIL and prior to the time it was used by Plaintiff, the Drug Company Defendants impliedly warranted to Plaintiff and to Plaintiff's physicians that the product was of merchantable quality and safe and fit for the use for which it was intended.

197. Plaintiff relied on the skill and judgment of the Drug Company Defendants in using RAMIPRIL.

198. RAMIPRIL was not safe and unfit for its intended use, nor was it of merchantable quality, as warranted by the Drug Company Defendants, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. RAMIPRIL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, RAMIPRIL proximately caused Plaintiff to sustain damages and injuries as alleged in this Complaint by virtue of causing Plaintiff's injuries.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for their injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 11

CONSTRUCTIVE FRAUD

199. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

200. Drug Company Defendants, while in possession of unique and pertinent information involving the safety and reliability of RAMIPRIL as sound, failed to warn of RAMIPRIL's inherent design, safety and manufacturing defects. Drug Company Defendants suppressed this information and continued sales and marketing of their drug to the general public. Drug Company Defendants

knew or should have known Plaintiff had no means, other than the full, accurate, and objective disclosure by Drug Company Defendants, to obtain the relevant information.

201. Through its unique knowledge and expertise regarding the affected nature of RAMIPRIL and through its statements to physicians and their patients in advertisement, promotional materials, and other communications, Drug Company Defendants professed and actively misrepresented that RAMIPRIL was safe for its intended use and was free from design, safety and manufacturing defects.

202. Drug Company Defendants misrepresentations and omissions were made intentionally to induce Plaintiff to purchase Drug Company Defendants drug in order to reap the high profit margin relating to Drug Company Defendant's RAMIPRIL.

203. Drug Company Defendants conduct took unconscionable advantage of its dominant position of knowledge, engaging in constructive fraud in its relationship with Plaintiff. Misled by this veil of fraud, Plaintiff reasonably relied on Drug Company Defendants representations regarding RAMIPRIL.

204. As a result, Plaintiff has suffered and will continue to suffer injuries, harm, and economic loss as alleged herein, including permanent injuries, and expenses attributable to their condition.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 12

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

205. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

206. Through intentional, reckless, and extreme conduct Drug Company Defendants knowingly denied Plaintiff adequate opportunity in measuring the level of risk related to Drug Company Defendants' RAMIPRIL drug. By withholding information of known design and manufacturing defects and concealing those fatal problems, Drug Company Defendants created a false sense of security for Plaintiff, who assumed reasonable safety with Drug Company Defendants drug RAMIPRIL.

207. Drug Company Defendants conduct of intentional omission, concealment, and failure to warn of the design and manufacturing defects caused Plaintiff to suffer injuries, harm, and economic loss as alleged herein, including a permanent and substantial injuries, and expenses attributable to Plaintiff's condition.

208. The injuries described above entitle Plaintiff to compensatory damages and equitable and declaratory relief, along with all appropriate damages according to proof.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff

for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 13

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

209. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

210. Drug Company Defendants intentionally and willfully failed to disclose or warn of the inherent risks and defects of RAMIPRIL to physicians and patients. Drug Company Defendants enforced its negligent conduct through manufacturing, marketing, and selling its defective drug to Plaintiff, while knowingly concealing design, manufacturing and safety defects, and misrepresenting the risks of severe side effects, quality, safety, and efficacy of the drug.

211. Drug Company Defendants willful conduct inflicted Plaintiff with severe emotional distress through Plaintiff's subsequent illness resulting from the use of RAMIPRIL.

212. Drug Company Defendant's conduct of willful omission and concealment of design, manufacturing and safety defects in order to induce ingestion of the drug caused Plaintiff severe emotional distress.

213. As a direct result of Drug Company Defendant's careless and negligent conduct, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including permanent and substantial injuries, and expenses attributable to his injuries.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 14
MEDICAL MONITORING

214. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

215. As a direct result of Drug Company Defendants actions, omissions, and negligence, Plaintiff has been put at a heightened risk of very serious health complications. The risk requires diagnostic medical examinations. By monitoring and testing the affected it can be determined whether Plaintiff is prone to serious health complications as a result to the damages caused by Drug Company Defendants. Such testing and monitoring may save Plaintiff's life.

216. Because of the risks, medical monitoring is the most appropriate method by which it can be determined whether Plaintiff should be promptly treated.

217. Plaintiff has no adequate remedy at law in that monetary damages alone cannot compensate them for the risk of additional surgeries and other treatments necessitated by the use of the drug. Without Court-approved medical monitoring, Plaintiff will continue to face an unreasonable risk of harm.

WHEREFORE, Plaintiff prays for judgment against Drug Company Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for his injuries in an amount, which will deter the Drug Company Defendants and others from like conduct.

COUNT 15
JOINT AND SEVERAL LIABILITY

218. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

219. By virtue of their individual and collective acts and omissions, Defendants are jointly and severally liable to Plaintiff as such acts and omissions have proximately caused Plaintiff to suffer a single indivisible injury for which each Defendant is responsible.

VI.

DAMAGES

220. As a direct and proximate result of the acts and omissions of the Drug Company Defendants, Plaintiff ingested RAMIPRIL, which was causally related to and contributed to Plaintiff's severe skin reaction and injuries resulting from the adverse reaction caused by Defendants drug.

221. As a direct and proximate result of the acts and omissions of the Drug Company Defendants, Plaintiff has suffered extreme emotional distress, anguish, physical and mental suffering, and is rendered physically disabled.

222. As a direct and proximate result of the acts and omissions of the Drug Company Defendants, Plaintiff experienced extreme embarrassment, shame, anguish, anxiety, and has sustained a loss of enjoyment of life.

223. Plaintiff seeks recovery of reasonable attorney's fees and treble damages pursuant to the Tennessee Consumer Protection Act.

224. Plaintiff seeks the recovery for past and future special damages, which includes medication, doctor, rehabilitation, therapy, and other assisted living, nursing care and loss of earning capacity. Plaintiff also seeks damages in the amount to be determined for the wrongful conduct of the Drug Company Defendants.

VII.

DEMAND FOR JURY TRIAL

225. Plaintiff hereby demands a trial by jury as to all issues so triable.

VIII.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Drug Company Defendants as follows:

226. For judgment for damages in the amount of $750,000 to compensate for damages, including but not limited to past, present, and future economic expenditures in connection with the injuries sustained by Plaintiff as a result of ingesting Drug Company Defendant's RAMIPRIL drug;

227. For compensatory damages according to proof;

228. For all applicable statutory remedies provided by that assert liability for Drug Company Defendants wrongdoings and improper conduct;

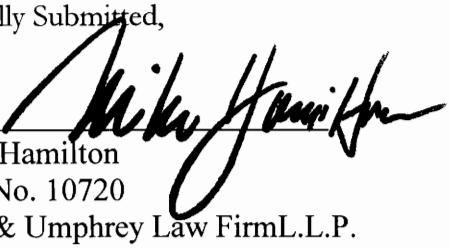
229. For a disgorgement of profits;

230. For prejudgment interest, as permitted by law;

231. For reasonable costs, including attorneys fees as permitted by law; and

232. For all other just and proper relief.

Respectfully Submitted,

BY: 

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